

**REMARKS**

Claims 1-51 are pending in the application. Claims 1-51 have been rejected. Claims 1, have been amended. No new matter has been added.

**Claim Rejections - 35 U.S.C. §102**

Claims 1-32 and 51 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,362,440 ("Karidis"). Claims 33, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Straka et al; Patient Self Reporting of Compliance Does not Correspond with Electronic Monitoring: An Evaluation Using Isosorbide Dinitrite as a Model Drug ("Straka"). Applicants respectfully traverse the rejection for the following reasons.

**Claims 1, 22, and 51**

Applicants respectfully disagree with the Examiner as to what claimed. In the Response to Arguments section the Examiner states that Applicants do not claim an instrument added to a paper diary. The Examiner appears to have not given weight to the recitation of "paper diary" throughout the claims. Indeed, Claim 1 recites "An instrumented paper diary for recording data." Claim 22, recites "an instrumented paper diary." Claim 26 recites "an electronic device for use with a paper diary" Claim 51 recites "A method of making an instrumented paper diary, comprising: providing a paper diary..." Indeed, every independent claim of the invention, as well as almost every dependent claim recites a paper diary. As such, Applicants do not agree with the Examiner's statement that "the prior art merely needs to teach an electronic instrument (electronic diary) for generating a record." This is simply not true.

In order for a reference to anticipate a claim under 35 U.S.C § 102, the reference must disclose each and every element of the claim. Karidis fails to disclose each and every element of claims 1, 22, and 51. Specifically Karidis fails to disclose a paper diary as set forth in claims 1, 22, and 51. Karidis makes no disclosure of a paper diary and instead discloses a portable computer with a recoding device. Also, the portable computer of Karidis does not generate a record of the use of the paper diary. It monitors the use of the device itself. Thus Karidis also

fails to disclose electronic instrumentation for generating an electronic record of diary use. As such Karidis fails to disclose each and every element of claims 1, 22, and 51.

In light of the foregoing arguments, Applicants respectfully submit that claims 1, 22 and 51 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 1, 22, and 51 under 35 U.S.C. §102, and pass the claim to allowance.

#### Claims 2-21 and 23-32

Claims 2-21 depend from claim 1 and claims 23-32 depend from claim 22. As such, claims 2-21 and 23-32 incorporate each and every element of claims 1 and 22 respectively. As set forth above, Karidis fails to disclose each and every element of claims 1 and 22. Therefore Karidis fails to disclose each and every element of claims 2-21 and 23-32.

Applicant do not disagree with the Examiner that any of the activities listed by the Examiner (opening and closing, moving, etc.) could be considered “use”. What the Applicants are arguing is the “use” of the recited paper diary. As Karidis fails to disclose a paper diary, Karidis also fails to disclose “use” of a paper diary since there is no paper diary to be used

In light of the foregoing arguments, Applicants respectfully submit that claims 2-21 and 23-32 are patentable over Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 2-21 and 23-32 under 35 U.S.C. §102, and pass the claims to allowance.

#### Claim 33

Straka fails to disclose each and every element of claim 33. Claim 33 recites “A method of monitoring subject compliance, comprising: detecting an event related to data entry in a paper diary for recording data; and capturing and storing a characteristic of the event to generate an electronic record of said data entry.” This is not disclosed by Straka. Straka discloses monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it

detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary and allows for the detection of such proactive or retroactive data entry. This is discussed as one of the advantages of the present invention (See Background of the Invention).

In light of the foregoing arguments, Applicants respectfully submit that claim 33 is patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claim 33 under 35 U.S.C. §102, and pass the claims to allowance.

#### Claims 38 and 39

Claims 38 and 39 depend from claim 33. As such, claims 38 and 39 incorporate each and every element of claim 33. As set forth above, Straka fails to disclose each and every element of claim 33. Therefore Straka fails to disclose each and every element of claim 38 and 39.

In light of the foregoing arguments, Applicants respectfully submit that claims 38 and 39 are patentable over Straka. Applicants therefore request the Examiner withdraw the rejection of claims 38 and 39 under 35 U.S.C. §102, and pass the claims to allowance.

#### Claim Rejections - 35 U.S.C. §103

Claims 34-37, 40, and 41 are rejected under 35 U.S.C. §103(a) as being unpatentable over Straka in view of Karidis. Claims 42-50 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hyland et al: Diary Keeping in Asthma: Comparison of written and Electronic methods ("Hyland"); further in view of Karidis. Applicant respectfully traverses the rejection for the following reasons.

#### Claims 34-37, 40, and 41

Claims 34-37, 40, and 41 all depend from claim 33 and as such incorporate each and every element of claim 33. As previously argued, Straka fails to teach or suggest each and every element of claim 33. Specifically, Straka fails to teach or suggest detecting an event related to data entry in a paper diary for recording data; and capturing and storing a characteristic of the

event to generate an electronic record of said data entry. Indeed Straka would appear to teach away from the present invention. Straka teaches monitoring the use of the vial that holds the medicine in the study. The MEMS vial in Straka only detects the opening and closing of the vial itself it does not detect the use of the paper diary. The MEMS vial cannot determine when a data entry is made in the paper diary. That is, the methodology of Straka can only detect if there is a discrepancy between the recorded usage of the vial and the diary. Straka cannot determine why there is a discrepancy. Using the methodology of Straka cannot detect proactive or retroactive data entry in a diary because it detects the usage of the vial not the diary. In contrast, the present invention tracks the usage of the diary allows for the detection of such proactive or retroactive data entry. Furthermore, Straka clearly set forth that the people being monitored where informed of what the vial did (monitor use). In contrast, one of the advantages of the present invention is that it is unobtrusive so that the diary user need not even be aware of the monitoring. Thus, Straka fails to teach or suggest each and every element of claim 33. The addition of Karidis fails to cure this deficiency. As discussed above, Karidis makes no mention whatsoever of a paper diary. As such, Karidis does not teach or suggest the recording of use of a paper diary. Thus neither Straka nor Karidis, alone or combined, teach or suggest each and every element of claim 33. As claims 34-37, 40, and 41 all depend from claim 33, neither Straka nor Karidis teach or suggest each and every element of claims 34-37, 40, and 41.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 34-37, 40, and 41 are patentable over Straka and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 34-37, 40, and 41 under 35 U.S.C. §103, and pass the claims to allowance.

#### Claim 42

Applicants respectfully disagree with what the Examiner asserts is taught in Hyland and claimed in claim 42. Applicants reassert that Hyland fails to teach or suggest each and every element of claim 42. Claim 42 is directed to a method of monitoring compliance by tracking paper diary use. This includes the step of generating an electronic record containing information regarding use of a paper diary for recording clinical trial data. As argued previously, Hyland does not teach a method for generating electronic records concerning a paper diary entry. The

study of Hyland involved the participants making two separate diary entries: one paper diary and one computer diary. The electronic records of the use of the paper diary were not generated. Usage was only tracked on the computer, not the paper diary. Combining the two methods of data entry (paper and computer) would have undermined the whole purpose of the study (comparing the two methods). Furthermore, as discussed above, Karidis makes no mention of a paper diary whatsoever. The device of Karidis is effectively the computer log in the Hyland study. Thus the combination of Karidis with Hyland does not cure the deficiencies of Hyland. As such neither Hyland nor Karidis alone or in combination teach or suggest each and every element of claim 42.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claim 42 is patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejection of claim 42 under 35 U.S.C. §103, and pass the claim to allowance.

#### Claims 43-46

Claims 43-46 depend from claim 42. As such claims 43-46 incorporate each and every element of claim 42. As discussed above the combination of Hyland and Karidis fails to teach or suggest each and every element of claim 42. Thus, the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 43-46.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 43-46 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejection of claims 43-46 under 35 U.S.C. §103, and pass the claims to allowance.

#### Claim 47

Applicants respectfully disagree with what the Examiner asserts is taught in Hyland and claimed in claim 47. Applicants reassert that Hyland fails to teach or suggest each and every element of claims 47. Claim 47 is directed to methods of monitoring compliance by tracking paper diary use. The method includes the step of providing a subject with an instrumented paper

diary for recording clinical trial data. There is no use of an *instrumented paper diary* in Hyland. The study of Hyland involved the participants making two separate diary entries: one paper diary and one computer diary. Usage was only tracked on the computer, not the paper diary. Combining the two methods of data entry (paper and computer) would have undermined the whole purpose of the study (comparing the two methods). Furthermore, as discussed above, Karidis makes no mention of a paper diary whatsoever. The device of Karidis is effectively the computer log in the Hyland study. Thus the combination of Karidis with Hyland does not cure the deficiencies of Hyland. As such neither Hyland nor Karidis alone or in combination teach or suggest each and every element of claim 47.

In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 42 and 47 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 42 and 47 under 35 U.S.C. §103, and pass the claims to allowance.

#### Claims 48-50

Claims 48-50 depend from claim 47. As such claims 48-50 incorporate each and every element of claim 47. As discussed above the combination of Hyland and Karidis fails to teach or suggest each and every element of claim 47. Thus, the combination of Hyland and Karidis fails to teach or suggest each and every element of claims 48-50.

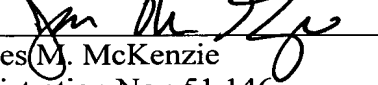
In light of the foregoing claim amendments and arguments, Applicants respectfully submit that claims 48-50 are patentable over Hyland and Karidis. Applicants therefore request the Examiner withdraw the rejections of claims 48-50 under 35 U.S.C. §103, and pass the claims to allowance.

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If, however, the Examiner considers that further obstacles to allowance of these claims persist, we invite a telephone call to Applicant's representative.

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Respectfully submitted,

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